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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/071,840	02/08/2002	Kathleen M. Miller	98-P0151	1381

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EXAMINER	
ISABELLA, DAVID J	

ART UNIT	PAPER NUMBER
3738	

DATE MAILED: 07/13/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

05

Office Action Summary	Application No.	Applicant(s)	
	10/071,840	MILLER ET AL.	
	Examiner	Art Unit	
	DAVID J ISABELLA	3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 April 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-4,6-47 and 70-80* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4,6-47 and 70-80* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Status of the Claims

Applicant's election of claims 1-47,70-72 in Paper No. 8 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claims 48-69 have been withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. These claims have been cancelled. Claim 5 has been cancelled. Claims 73-80 have been newly added. Currently claims 1-4,6-47,70-80 are pending for action.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-4,6-8,13-19, 72-80 are rejected under 35 U.S.C. 103(a) as being unpatentable over Terry, et al (6596401) in view of Farber (5366505) and Darouiche (6475434).

Terry, et al discloses providing an implantable and/ or insertable medical device with at least one biocompatible matrix polymer region and bioactive agents comprising

an antimicrobial agent and a biofilm synthesis inhibitor. While Terry, et al discloses the use of coating for incorporating the various agents, Farber teaches that the agents may be added to the substrate by spraying, dipping soaking or by incorporated directly into the substrate material of the device. To incorporate the agents into the substrate material and/or into a coating that is applied onto the substrate of Terry et al would have been obvious from the teachings of Farber. The incorporation of the agents into the substrate of the device would meet the newly added limitation of "medical device comprises at least one biocompatible matrix polymer region that is not a coating". Whether the material is extruded or formed by other methods eg. casting, the device is essentially identical. The agent may be added during the process or after the process and the final product would be essentially the same. To incorporate the agent of Terry, et al according to the teachings of Farber would yield the final product as broadly claimed by applicant. It is not clear how the added process steps of extrusion further defines the device of applicant.

Claims 2 and 3, the biofilm inhibitor may be present on one surface of the device or over multiple surfaces of the device (see column 17 of Terry et al).

Claim 4, see rejection to claim 1.

Claim 6, the biofilm inhibitor may be present on one surface of the device or over multiple surfaces of the device (see column 17 of Terry et al).

Claim 7, see columns 5, lines 66+ of Darouiche.

Claim 8, see column 6, lines 1+ of Darouiche.

Claims 13 and 14, see column 17, lines 43+ of Dariouche.

Claim s 15-19, see any examples 1-3 of Darouiche.

Claims 72-80, see device of Terry, et al as modified.

Claims 9,10,11,12,26-42,70,71 are rejected under 35 U.S.C. 103(a) as being unpatentable over Terry et al (6596401) in view of Farber (5366505) and Darouiche (6475434) as applied to claim1 above, and further in view of Helmus, et al (5569463) or Zaffaroni et al (4036227).

While Terry et al discloses a general listing of materials that may be used as the base matrix, including ethylene and acetate compositions, the use of ethylene vinylacetate is not specifically disclosed. Helmus, et al and Zaffaroni et al teaches a listing of materials that may be used as a base matrix for medical devices including ethylene and acetate compositions including ethylene vinylacetate composition and degradable materials including polylactic and polyglycolic acids. If not inherent in Terry et al, the use of ethylene vinyl acetate as a base matrix for medical devices would have been obvious from the teachings of Helmus, et al or Zaffaroni et al based upon the use of equivalent materials depending upon the engineering constraints of the particular application of the device.

Claims 26-33,70,71 see Zaffaroni, et al. The use of a barrier layer to control the release of the active agents is taught by Zaffaroni, et al. The annulus shape see the appropiate figures of Zaffaroni,et al. The composition of the matrix polymer region, see Terry et al as modified by either of Helmus or Zaffaroni et al.

Claims 34-42, see disclosure of intended devices in each of Terry, et al, Darouiche, Helmus and Zaffaroni et al.

Claims 20-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Terry et al (6596401) in view of Farber (5366505) and Darouiche as applied to claim 1 above, and further in view of Braden (5468787).

Terry et al does not disclose the use of a medical device with a base matrix having radioopacifying agent incorporated therewith. Braden teaches a medical device with a base polymer matrix with biocidal agents having radioopacifying agent incorporated therewith to provide contrast of the device for surgical positional verification by the surgeon. To complex radioopacifying agent, barium sulfate with the base matrix of Terry et al to to provide contrast of the device for surgical positional verification by the surgeon would have been obvious to one with ordinary skill in the art from the teaching of Braden.

Claims 23-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Terry et al (6596401) in view of Farber (5366505) and Darouiche as applied to claim 1 above, and further in view of Capelli (5607683).

Terry et al does not disclose the use of a medical device with a base matrix having therapeutic agent incorporated therewith. Capelli teaches a medical device with a base polymer matrix with biocidal agents having therapeutic agent incorporated therewith to prevent infections in the wounds when employing the device in vivo. To

complex a therapeutic agent with the base matrix of Terry et al to prevent infection at the wound site would have been obvious to one with ordinary skill in the art from the teaching of Capelli.

Claims 43-47 are rejected under 35 U.S.C. 103(a) as being unpatentable over Terry et al (6596401) in view of Farber (5366505) and Darouiche as modified by the secondary references as applied to claim 35 above, and further in view of Redkar (6482830).

While the specific medical device of a pancreatic stent is not specifically disclosed by Terry et al as modified, Redkar teaches the use of a catheter or a stent for treatment to the pancreas wherein the device comprises a bicarbonate buffering agent. The use of a stent of Terry et alas modified by the secondary references to treat the pancreas wherein the stent comprises buffering agents would have been obvious to one with ordinary skill in the art from the teachings of Redkar in order to obviate the needs of an indwelling catheter thereby reducing the risk of infections.

Claims 72-76, is rejected under 35 U.S.C. 103(a) as being unpatentable over Terry et al (6596401) in view of Farber (5366505) and Darouiche,et al in view of Helmus, et al , Zaffaroni et al and Braden.

Terry et al discloses providing an implantable medical device with at least one biocompatible matrix polymer region and bioactive agents comprising an antimicrobial agent and a biofilm synthesis inhibitor. While Terry et al discloses a general listing of

materials that may be used as the base matrix, including ethylene and acetate compositions, the use of ethylene vinylacetate is not specifically disclosed. Helmus, et al and Zaffaroni et al teaches a listing of materials that may be used as a base matrix for medical devices including ethylene and acetate compositions including ethylene vinylacetate composition and degradable materials including polylactic and polyglycolic acids. If not inherent in Terry et al, the use of ethylene vinyl acetate as a base matrix for medical devices would have been obvious from the teachings of Helmus, et al or Zaffaroni et al based upon the use of equivalent materials depending upon the engineering constraints of the particular application of the device. Terry et al does not disclose the use of a medical device with a base matrix having radioopacifying agent incorporated therewith. Braden teaches a medical device with a base polymer matrix with biocidal agents having radioopacifying agent incorporated therewith to provide contrast of the device for surgical positional verification by the surgeon. To complex radioopacifying agent, barium sulfate with the base matrix of Terry et al to provide contrast of the device for surgical positional verification by the surgeon would have been obvious to one with ordinary skill in the art from the teaching of Braden.

Response to Arguments

Applicant's arguments with respect to the claims have been considered but are moot in view of the new ground(s) of rejection. Applicant has amended the claims to further define the device as comprising at least one biocompatible matrix polymer region that is not a coating. Examiner has applied new art to Terry, et al and Farber which in

combination teaches the combination of the antimicrobial agent and the biofilm inhibitor which may be incorporated into the substrate of the device.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to DAVID J ISABELLA whose telephone number is 703-308-3060. The examiner can normally be reached on MONDAY-FRIDAY.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, CORRINE MCDERMOTT can be reached on 703-308-2111. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

DAVID J ISABELLA
Primary Examiner
Art Unit 3738

DJI
7/09/2004